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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,872	03/30/2004	Dominique Charmot	RLY 04031.102	5573

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EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
05/04/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary	Application No.	Applicant(s)	
	10/813,872	CHARMOT ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,17,22-24,31,32,45-56,58-65 and 67-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 17, 22-24, 31, 32, 45-56, 58-65, and 67-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Response dated 12/28/09.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 17, 22-24, 31, 32, 45-56, 58-65, and 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Notenbomber (EP 0 730 494 hereafter '494) in view of Macek et al (USPN 3,499,960 hereafter '960) and Bogentoft (EP 0 040 590 hereafter '590).

The '494 patent discloses a particle formulation comprising a core and a coating where the core comprises a cation exchange resin and the coating does not disintegrate during passage through the intestinal tract of humans and where the membrane is more permeable to monovalent cations rather than bi-or higher cations (page 1, lin. 49-55). The particles can be mixed with sodium chloride as an excipient and administered orally as a foodstuff (page 2, lin. 54-60). The

particles are safe means of absorbing cations from the digestive tract, encapsulating the ions and removing them as waste from the body (page 2, lines 8-12). The cation exchange materials come from a wide range of sources and can include sulphonated crosslinked polystyrenes, polycarboxylates, polymaleinates, polyacrylates and polyphosphates (page 2, lin. 20-34). The cation exchange resin of the reference can be used to remove potassium ions from a variety of sources (page 3, lin. 10-12). The coatings include polyethyleneimine and known surfactants (page 2, lin. 42-45; example 2). The particles can be further coated with cellulose acetate a well known enteric polymer (example 1). The reference is silent to the specific monomers of the instant claims. The particles are microcapsules that range in size from 0.01-10 mm in size, with specific ranges of approximately 290 microns (page 2, lin. 41-42; Example 1). The particles can be formulated in various pharmaceutical forms including tablets, pills and capsules (page 3, lines 15-18).

The ‘494 patent differs from the instant claims in that the reference is silent to the specific coating materials of the instant claims. The coating of ionic exchange resins with crosslinked polymers is well known in the art as seen in the '960 patent.

The ‘960 patent discloses a coated ionic exchange resin (abstract). The ionic exchange resin is a crosslinked polystyrene based polymer that binds bile in the gastrointestinal tract (col. 1, lin. 20-55). The particles have a size less than 149 microns (col. 2, lin. 65-70) and are coated with crosslinked synthetic polymer such as Carbopol, a crosslinked acrylic polymer (col. 3, lin. 5-20). It would have been obvious to coat the ionic exchange resins of the ‘494 patent with the polymers of the ‘960 patent since both patents solve the problem of binding ions in the gastrointestinal tract.

The '494 patent differs from the instant claims in that they are silent to the total thickness of the coating materials in the instant claims. The coating of an ionic exchange resins with polymers of a specific thickness is well known in the art as seen in the '590 patent.

The '590 patent discloses an ionic exchange resin particle comprising a methacrylic polymer (abstract). The coatings comprise Eudragit RL and RS with a thickness from 10-30 microns (page 3, lin. 19-36). The ionic exchange resin comprises a crosslinked carboxylic based polymer (page 3, lin. 15). It would have been obvious to apply the acrylic polymer to the ionic exchange resin of the combination in order to provide an even and stable formulation that allowed ions to pass through.

Regarding the treatment of hyperkalemia, it would have been obvious to treat hyperkalemia with the combined prior art. Hyperkalemia is a condition characterized by high potassium ions. The combined prior art comprises the ion exchange resin of the '494 patent coated by the coating of the '960 patent. The resins of the '494 patent bind excess potassium and require a coating that is more permeable to those ions. The coatings of the '960 patent are used for binding bile in the GI tract, bile comprising potassium ions, and would have been an obvious addition to a potassium binding particle. With these things in mind it would have been obvious to treat a potassium disorder with a formulation that binds excess potassium ions.

Regarding the binding and retention of the potassium ion in the particles, it is the position of the Examiner that combination of the prior art would inherently bind and retain the claimed amount of potassium. The instant claims recite core-shell particles comprising a styrene based cation exchange resin coated with a crosslinked synthetic polymer in a specific thickness. The '494 patent discloses a core-shell particle formulation comprising a core of styrene based cationic

exchange resin useful for binding potassium. The particles can be coated with any material that is permeable to potassium ions and discloses cellulose acetate. The '960 patent discloses a core-shell ion exchange resin useful for binding bile (comprising potassium ions) where the shell is a crosslinked acrylic polymer, and the ‘590 patent discloses that these polymers can be applied in a specific thickness. Each component is identical to the instant claims and would have been an obvious modification since each patent solves the same problem of binding potassium ions and retaining them in the particle. As such since a composition and its properties cannot be separated the same components must also retain up to 75% of the potassium within the particle.

With these things in mind it would have been obvious to combine the coatings of the '960 patent onto the ‘494 patent since both patents solve the same problem of binding ions in the gastrointestinal tract. The ion exchange resins of the '960 patent bind bile in the gastrointestinal tract. Bile comprises potassium ions and will be bound by the formulation of the '960 patent. It would have been obvious to coat the potassium binding resins of the ‘494 patent also because the polymers are both styrene based. It would have been obvious to apply the coating of the '960 patent to a thickness as disclosed in the '590 patent. This would have been an obvious adjustment since both patents solved the same problem of coating ionic exchange resin with methacrylic and acrylic polymers. The ionic exchange resins would have been coated with the polymers of the ‘494 patent to the thickness of the ‘590 patent in order to allow the potassium ions to pass through the membrane as suggested by the ‘494 patent. One of ordinary skill in the art would have been motivated to coat the particles of the ‘494 patent with the coatings of the ‘960 patent in order to provide protection tot eh resin in the gastrointestinal tract. It would have

been obvious to combine the prior art with an expected result of a stable potassium binding formulation useful for treating high potassium related conditions.

Response to Arguments

Applicant's arguments filed 12/28/09 have been fully considered but they are not persuasive. Applicant argues that:

The combination of the prior art would not obviate the instant claims since the combination does not provide a core shell particle as described in the instant claims.

Regarding this argument it remains the position of the Examiner that the combination of the prior art continues to obviate the instant claims. The ‘494 patent provides an oral pharmaceutical composition comprising a core-shell format comprising a shell and a cation exchange core. The core is a cation exchange resin that can bind potassium, calcium and sodium. The resins include sulphonated crosslinked polystyrenes, polycarboxylates, polymaleinates, polyacrylates and polyphosphates, and are administered orally and do not disintegrate in the intestinal tract. The cation resins are coated with a shell comprising polyethyleneimine and additionally enteric polymers. Theses polymers are different from the instant claims, however crosslinked synthetic polymer used as shells for ion exchange resins are known in the prior art as seen in the '960 patent. Applicant argues that since the '960 patent is concerned with anionic exchange resins and their absorption the '960 patent is unrelated to the instant invention. However the patent is used to show the level of skill in the art regarding crosslinked synthetic shell polymers used in ionic exchange and removal. The ‘960 patent provides a core-shell structure comprising a shell such as Carbopol and is used to remove bile acids from the intestinal

tract of a patient in need thereof. The patent establishes the level of skill in the art regarding the removal of compounds and ions from the GI tract using non-disintegrating core-shell formulations. The patents are within the same field of endeavor and solve the same problem of removing ions from the GI tract without disintegrating. The combination is silent to the thickness of the instant claims, however the optimization of the shell portion of a ion binding core-shell structure is well within the level of skill in the art as seen in the '590 patent. The '590 patent discloses an ionic exchange resin that is coated with a synthetic polymer in a thickness of 10-30 microns. It would have been obvious to optimize the thickness as seen in the '590 patent since the reference discloses ion binding using similar compounds such as resin with crosslinked carboxylic base' polymer and enteric crosslinked shells. It would have been obvious to follow the suggestions of the '497 patent and apply the coating of the '540 patent since both patents solve the same problem of ion removal from the gastrointestinal tract. It would have been obvious to optimize the thickness of the shell in order to properly encapsulate specific ions.

Regarding the method of treating hyperkalemia, it remains the position of the Examiner that the combination would be useful in a method of ion removal. The instant method claims recite a single step of administration, with the function of the core-shell dependent on the disposition of the core-shell polymers. The combination discloses the same core-shell disposition as the instant claims, specifically a core comprising a sulphonated crosslinked polymer such as polystyrenes, polycarboxylates, polymaleinates and polyphosphates, coated with a shell comprising crosslinked synthetic polymers such as Carbopol, optimized to a specific thickness. The combination provides an oral administration method that removes desired ions from the gastrointestinal tract. As the core portions are identical to the instant claims, these

polymers would bind the potassium in the GI tract and effectively reduce the potassium level of the patient. This removal of ions would provide an effective treatment of hyperkalemia. For these reasons the claims remain obviated.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
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/MICAH-PAUL YOUNG/
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